

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1) Submitter
name, address,
contact**

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Jennifer Tribbett

Date Prepared: May 31, 2000

2) Device Name Proprietary Name: OnTrak TesTcup Pro-5

Classification Name	Code	CFR	Predicate Device Name	Predicate 510(k) Number
Cocaine Test System	91DIO	862.3250	OnTrak TesTcup	K962411
Cannabinoid Test System	91LDJ	862.3870	OnTrak TesTcup	K962411
Morphine Test System	91DJJ	862.3640	OnTrak TesTcup	K962411
Methamphetamine Test System	91LAF	862.3610	OnTrak TesTstik Methamphetamine	K000096
Benzodiazepines Test System	91JXM	862.3170	OnTrak TesTstik Benzodiazepines	K983174

**3) Predicate
device**

We claim substantial equivalence to the currently marketed devices indicated above.

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**4) Device
Description**

The OnTrak TesTcup Pro-5 assay contained in this submission is an *in vitro* diagnostic test intended for professional use in the qualitative detection of cocaine (300 ng/ml), morphine (300 ng/ml), THC (50 ng/ml), methamphetamine (500 ng/ml) and benzodiazepines (100 ng/ml) in urine.

The TesTcup assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

Urine is collected directly in the OnTrak TesTcup Pro-5. After closing the cap and moving it to the "TEST" position, the sample reservoir is filled by tilting the cap. Urine then flows through a membrane by capillary action and reacts with antibody-coated microparticles and drug conjugate present on the membrane. In the absence of drug, the antibody is free to interact with the drug conjugate, causing the formation of a blue band ("negative" sign).

When drug is present in the specimen, it binds to the antibody-coated microparticles. If sufficient drug is present, the micro-particles are inhibited from binding the drug conjugate and no blue band is formed at the result window. A positive sample caused the membrane to remain white ("positive" sign).

An additional antibody/antigen reaction occurs at the "TEST VALID" area. The "TEST VALID" blue band forms when antibodies, which are imbedded in the reagent membrane, bind to the antigen on the blue microparticles. The presence of the "TEST VALID" band indicates that the test has completed, the reagents in the "TEST VALID" area are valid, and the results are ready to interpret.

**5) Technology
Characteristics**

TesTcup Pro-5 contains five individual, independent test chambers where the membranes, immobilized with drug conjugates, are inserted. Each individual membrane contained in the Pro-5 device, with the exception of Benzodiazepines (100 ng/ml), has been previously reviewed by FDA under the 510(k) numbers indicated in section 2 of this 510(k) summary. In other words, the same functional membranes (strips) for Cocaine, THC, Morphine and Methamphetamine contained in the predicate devices have now been inserted into the TesTcup Pro-5 chambers.

The Benzodiazepines membrane with a 200 ng/ml cutoff was previously reviewed under K983174. The Benzodiazepines membrane for Pro-5 has been modified to a 100 ng/ml cutoff level.

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**6) Substantial
Equivalence**

The TesTcup Pro-5 device has the **same intended use** and incorporates the **same fundamental scientific technology** as the predicate devices.

Topic	OnTrak TesTcup Pro-5	Predicates: TesTcup, TesTstik Methamphetamine, TesTstik Benzodiazepines
Intended Use	Qualitative detection of cocaine, cannabinoids, morphine, methamphetamine and benzodiazepines in urine.	Same
Scientific Technology	Microparticle capture inhibition	Same
Sample Matrix	Urine	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 1 0 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer L. Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K001356
Trade Name: OnTrak TesTcup Pro-5
Regulatory Class: II
Product Code: DJC
Dated: May 31, 2000
Received: June 5, 2000

Dear Ms. Tribbett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

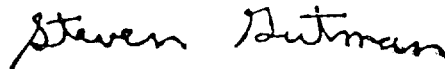
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):


Device Name: OnTrak TesTcup Pro-5

Indications for Use:

OnTrak TesTcup Pro-5 is an in-vitro diagnostic test intended for professional use for the qualitative detection of cocaine (300 ng/ml), morphine (300 ng/ml), THC (50 ng/ml), methamphetamine (500 ng/ml) and benzodiazepine (100 ng/ml) in urine.

OnTrak TesTcup Pro-5 provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method.

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 1001356

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)